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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,477	09/11/2006	Charles Y.F. Young	07039-489US1	9361

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FISH & RICHARDSON P.C.  
PO BOX 1022  
MINNEAPOLIS, MN 55440-1022

EXAMINER
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SZNAIDMAN, MARCOS L

ART UNIT	PAPER NUMBER
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1612

NOTIFICATION DATE	DELIVERY MODE
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05/29/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/567,477	<b>Applicant(s)</b> YOUNG, CHARLES Y.F.	
	<b>Examiner</b> MARCOS SZNAIDMAN	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This office action is in response to applicant's reply filed on March 17, 2009.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

#### ***Status of Claims***

Claims 1-2 are currently pending and are the subject of this office action.

Claims 1-2 are currently under examination.

#### ***Priority***

The present application is a 371 of PCT/US04/25336 filed on 08/04/2004, and claims priority to provisional application No. 60/492,367 filed on 08/04/2003.

#### ***Rejections and/or Objections and Response to Arguments***

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated (Maintained Rejections and/or Objections) or newly applied (New Rejections and/or

Art Unit: 1612

Objections, Necessitated by Amendment or New Rejections and/or Objections not Necessitated by Amendment). They constitute the complete set presently being applied to the instant application.

***Claim Rejections - 35 USC § 103 (Maintained Rejection)***

1) Claim 1 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Helmbrook et. al. (US 2002/0042375) in view of Kim et. al. (American Journal of Pathology, 2002, 160:219-226).

2) Claim 2 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Helmbrook et. al. (US 2002/0042375) and Kim et. al. (American Journal of Pathology, 2002, 160:219-226) as applied to claim 1 above, and further in view of Nakao et. al. (US 2002/0107273).

The reasons for this rejection have been provided in the previous office action dated September 17, 2008, the text of which is incorporated by reference herein.

Applicant's arguments have been fully considered but are not persuasive.

Applicant arguments are similar to the ones previously presented and have been addressed in previous office actions: Applicant does not dispute that the effect of NSAIDs on the expression of the Androgen Receptor (AR), the transactivating ability of the AR, and/or IL6-mediated activation of the AR may have been an inherent property of prostate cells exposed to NSAIDs. However, the pending claims require an active step

Art Unit: 1612

of "determining the level of expression, the transactivation ability, and/or the IL6-mediated activation of an androgen receptor". Since the mechanism of action of NSAIDs on prostate cancer cells was not known prior to the instant disclosure, the active step of "determining the level of expression, the transactivating ability, and/or the IL6-mediated activation of an AR" was not inherent in the references cited by the Examiner. In fact, there is no disclosure in any of the references cited by the Examiner that would prompt one of skill in the art to determine the level of expression, the transactivation ability, and/or the IL6-mediated activation of an AR.

Examiner's response: even though the mechanism of action of NSAIDs on prostate cells was not known prior to Applicant's instant disclosure, it was known that the level expression of the AR in prostate cells is directly correlated with the proliferation of prostate cancer cells: Kim et. al. (American Journal of Pathology (2002) 160:219-226, cited in previous office action) teach that the reduction of the level of expression of the Androgen Receptor (AR) is directly correlated to a decreased cell volume, apoptosis and decline in serum prostate-specific antigen (PSA, a well known marker for prostate cancer) (see page 219, from left column, last three lines through right column, first two lines). In other words, it will be obvious to monitor the level of expression of the AR and correlate it to the effectiveness of any prostate cancer treatment (including castration of nude mice as taught by Kim et. al., or by treatment with NSAIDs as in the instant application), regardless of the mechanism of action.

### ***Conclusion***

No claims are allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is

Art Unit: 1612

(571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/  
Examiner, Art Unit 1612  
May 15, 2009.

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612